

most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(2) *Organization for Economic Co-Operation and Development (OECD) protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part. Applicants should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(e) *Combining studies.* Certain toxicology studies may be combined to satisfy data requirements. For example, carcinogenicity studies in rats may be combined with the rat chronic toxicity study. Combining appropriate studies may be expected to reduce usage of test animals as well as reduce the cost of studies. EPA encourages this practice by including standards for acceptable combined tests in the Pesticide Assessment Guidelines. Registrants and applicants are encouraged to consider combining other tests when practical and likely to produce scientifically acceptable results. Registrants and applicants, however, must consult with the EPA before initiating combined studies.

**§ 158.75 Requirements for additional data.**

The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of the pesticide.

**§ 158.80 Use of other data.**

(a) *Data developed in foreign countries.* With certain exceptions, laboratory and field study data developed outside the United States may be submitted in support of a pesticide registration. Data generated in a foreign country which the Agency will not consider include, but are not limited to, data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. Applicants submitting foreign data must take steps to ensure that U.S. materials are used, or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the U.S. material or test site. Once submitted, the Agency will determine whether or not the data meet the data requirements.

(b) *Data generated for other purposes.* Data developed for purposes other than satisfaction of FIFRA data requirements, such as monitoring studies, may also satisfy data requirements in this part. Consultation with the Agency should be arranged if applicants are unsure about suitability of such data.

**Subpart B—How To Use Data Tables**

**§ 158.100 Pesticide use patterns.**

(a) *General use patterns.* There are six broad use categories used in the data tables. The six broad categories include terrestrial outdoor uses, aquatic outdoor uses, greenhouse uses, forestry uses, residential outdoor uses, and indoor uses of all types. The 6 broad use categories are further subdivided into 12 general use patterns which are the bases for data requirements established by use pattern. Within the data tables, general use patterns have been combined into single columns when the data requirements are the same for the combined uses. If there are no data requirements for a specific use, the column for that use is not included in the table. The 12 general use pattern groups used in the data table in this part are:

- (1) Terrestrial food crop use.
- (2) Terrestrial feed crop use.

- (3) Terrestrial nonfood crop use.
- (4) Aquatic food crop use.
- (5) Aquatic nonfood use.
- (6) Greenhouse food crop use.
- (7) Greenhouse nonfood crop use.
- (8) Forestry use.
- (9) Residential outdoor use.
- (10) Residential indoor use.
- (11) Indoor food use.
- (12) Indoor nonfood use.

(b) *Pesticide use site index.* The Pesticide Use Site Index is a comprehensive list of specific pesticide use sites. The index is alphabetized separately by site for all agricultural and all non-agricultural uses. The Pesticide Use Site Index associates each pesticide use site with one or more of the 12 general use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index, which will be updated periodically, is available from the Agency or may be obtained from the Agency's website at <http://www.epa.gov/pesticides>.

(c) Applicants unsure of the correct use pattern for their particular product should consult the Agency.

EFFECTIVE DATE NOTE: At 78 FR 26978, May 8, 2013, § 158.100 was amended by revising the heading of paragraph (a); revising paragraph (b); redesignating paragraph (c) as paragraph (e); revising newly redesignated paragraph (e); and adding new paragraphs (c) and (d), effective July 8, 2013. For the convenience of the user, the added and revised text is set forth as follows:

#### § 158.100 Pesticide use patterns.

(a) *General use patterns for conventional, biochemical, and microbial pesticides.* \* \* \*

(b) *Pesticide use site index for conventional, biochemical, and microbial pesticides.* The Pesticide Use Site Index for Conventional, Biochemical, and Microbial Pesticides is a comprehensive list of specific pesticide use sites. The index is alphabetized separately by site for all agricultural and all nonagricultural uses. The Pesticide Use Site Index associates each pesticide use site with one or more of the 12 general use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index for Conventional, Biochemical, and Microbial Pesticides will be updated periodically, and is available from the Agency or may be obtained from the Agency's Web site at <http://www.epa.gov/pesticides>.

(c) *Antimicrobial pesticide use patterns.* The general use patterns for antimicrobial pesticides are described in § 158.2201.

(d) *Pesticide use site index for antimicrobial pesticides.* The Pesticide Use Site Index for Antimicrobial Pesticides is a comprehensive list of specific antimicrobial use sites. The index is alphabetized by antimicrobial use sites, and associates each antimicrobial use site with one or more of the antimicrobial use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index for Antimicrobial Pesticides will be updated periodically, and is available from the Agency or may be obtained from the Agency's Web site at <http://www.epa.gov/pesticides>.

(e) *Determination of use pattern.* Applicants unsure of the correct use pattern for their particular product should consult the Agency.

#### § 158.110 Required and conditionally required data.

The tables in this part use the descriptors R (required), CR (conditionally required), and NR (not required) as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual applicability of the data requirement.

(a) EPA requires data designated as "required" (R) for products with a given use pattern in order to evaluate the risks or benefits of a product having that use pattern under any conditions established by the test notes.

(b) Data designated as "conditionally required" (CR) for products with a given use pattern are required by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the notes accompanying the requirement. The determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (for example, tier testing). Applicants must evaluate each applicable test note for the conditions and criteria to be considered in determining whether conditionally required data must be submitted.